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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,476	01/21/2004	Steven Bernard	JHN-3659-79	9797

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/760,476	BERNARD ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the middle section with a diameter larger than the end sections as set forth in claim 8 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,494,693 to Sunden.

In the specification and figures, Sunden discloses the device substantially as claimed by applicant. Sunden discloses a pump tube 10 comprising a first end 12A with a first inside diameter (see FIG 2D), a narrow center section of the tube 14 with a minor diameter (see 16 in FIG 2B) narrower than the first diameter that helps to push fluid through the tube during pumping operations(see column 7, lines 28-45). Sunden further illustrates a tapered tube transition section between the first end and the narrow section (unlabeled, see FIG 2A), and a second end 12B with an inside diameter the same size as end 12A. Sunden discloses that the tube is used to pass sensitive biological materials therethrough, which may include blood (see column 1, lines 23-25).

Sunden fails to disclose the proportional length of the tubing sections. Sunden disclosed that the length, shape, and overall proportions of tube sections are variable according to the shape and size of the pump used (see Sunden, column 13, line 57 to column 14 line 14). These teachings indicate that the length of the tubing and the length of the sections of various diameter are result-effective variables that depend on the configuration of the pump being used with the tubing. It has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art. See MPEP 2144.05 (II)(A) It has also been held that where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See MPEP 2144.04(I)(A). In the instant case, it is the position of the examiner that since Sunden discloses that the dimensions of the tube lengths are variable, and there is no evidence that the sizes claimed by applicant perform differently, providing unexpected results, than the device suggested in the prior art, applicant's claimed proportions are an obvious variation of the prior art.

4. Claims 1, 2, 4-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,494,693 to Sunden in view of US 4,954,055 to Raible et al.

In the specification and figures, Sunden discloses the device substantially as claimed by applicant. With regard to claims 1-2, 15, 19, Sunden discloses a pump tube 10 comprising a first end 12A with a first inside diameter (see FIG 2D), a narrow center section of the tube 14 with a minor diameter (see 16 in FIG 2B) narrower than the first diameter. The narrower diameter helps to prevent backflow in situations where a backpressure may develop, such as in the case of a clogged filter (see column 7, lines 5-10). Sunden further illustrates a tapered tube transition section between the areas of different diameters (see FIG 2A). Sunden discloses that the tube is used to pass

sensitive biological materials therethrough, which may include blood (see column 1, lines 23-25).

Sunden fails to disclose that the center pump section of the tube comprises an area of increased diameter. Raible discloses a pump tube with narrow end sections 16, 18, and a center section 20 of increased diameter, with tapered sections in between, wherein the area of increased diameter provides for less turbulent pumping of blood through the pumping section of the tube (see column 1, lines 20-31, column 2, lines 13-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a small area of increased diameter as disclosed by Raible to the pump tube disclosed by Sunden in order to prevent backflow as taught by Sunden, while decreasing hemolysis, as taught by Raible.

With regard to applicant's recitation of the length of the increased and decreased diameter sections as a percentage of the total tube length, discrete lengths of the sections, and relative diameters (see claims 1, 4, 8, 14, 15, 19, 31), both Sunden and Raible disclose that the length, shape, and overall proportions of tube sections are variable according to the shape and size of the pump used (see Sunden, column 13, line 57 to column 14 line 14; Raible column 3, lines 38-43). These teachings indicate that the length of the tubing and the length of the sections of various diameter are result-effective variables that depend on the configuration of the pump being used with the tubing. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art. See MPEP 2144.05 (II)(A) It has also been held that where the only difference

between the prior art and the claims is a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See MPEP 2144.04(I)(A). In the instant case, it is the position of the examiner that since Sunden and Raible disclose that the dimensions of the tube lengths are variable, and there is no evidence that the sizes claimed by applicant perform differently than the device suggested in the prior art, applicant's claimed proportions are an obvious variation of the prior art.

With regard to claims 2 and 7, Raible illustrates that the wider middle section engages with a pump, illustrating that the narrower sections are not engaged with a pump (see FIG 1).

With regard to claims 5, 16, 17, 21, and 22, Sunden illustrates that all sections of the pump tube comprise substantially the same wall thickness (see Sunden FIGS 2B, 2C, 2D), and Raible indicates that the tube wall 26 remains "substantially constant" throughout the length of the tube (see Raible column 3, lines 16-19).

With regard to claims 6 and 20, Sunden discloses that the inner diameter of the fluid passageway of the reduced diameter pump section may range from 0.1 to 4mm, meeting applicant's claim drawn to a diameter of 0.06in (see column 12, lines 55-67). Sunden further discloses that the outer diameter of the normal diameter, non pump portion of the tube will range from 12-16mm, with the outer diameter of the pump section will range from 2-18mm (see column 13, lines 1-10). Sunden illustrates the outer

diameter of the pumping section to be smaller than that of the larger section, meeting the limitations of applicant's claims (see FIGS 2A-2D).

With regard to claims 9-12, 18, 23, 24, and 26, Sunden discloses that first and second ends of the single-lumen tube are attachable to a connector (not shown, see column 7, lines 19-25). Sunden further illustrates that the transition from the wide section to the narrow section is a smooth transition, teaching that abrupt changes in the direction of the tube (such as sharp turns or edges) should be avoided (see FIG 2A, column 7, lines 40-48).

With regard to claims 13 and 25, Sunden discloses that the tube may be manufactured from PTFE, which is a biocompatible polymer (see column 12, lines 8-25).

With regard to claims 27 and 28, Sunden discloses that the tube is used to pass sensitive biological materials therethrough, which may include blood (see column 1, lines 23-25).

Response to Arguments

5. Applicant's traversal of the Examiner's objection to the drawings is unpersuasive. While Applicant is correct that the drawings are not required to be to scale or show particular dimensions, they are required to show **every feature** of the invention specified in the claims. Applicant specifically sets forth a limitation that the middle section of the tube (section 230 in FIG 3) comprises a **larger** diameter than the end sections 150. Such a limitation claims a difference in relative size of the tube sections,

which is not illustrated by the drawings. Since the claims set forth a difference in the relative dimensions of the tubing sections, the drawings **must** also illustrate a difference in the relative dimensions of the tubing sections.

6. Applicant's arguments, filed 5 July 2007, with respect to the rejection(s) of claim 29 under 35 USC 102(b) over Sunden have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 USC 103 over Sunden.

7. Applicant's arguments with regard to the 35 USC 103 rejection over Sunden have been fully considered but they are not persuasive. Applicant argues that Sunden does not suggest a narrow diameter section of the tube that is distinct from the pump tube section, contrary to the tube recited in claims 29 and 30 that has a pump tube section and a narrow tube section that is not part of the pump tube section. Examiner respectfully disagrees. Applicant does NOT claim that the narrow tube section is not part of the pump tube section. In fact, in claim 29, line 9 and claim 30, line 9, applicant claims a "pump tube section integral to the narrow section." This claim specifically sets forth that the pump tube section and the narrow section are the same section of tubing, which is a limitation disclosed by Sunden.

8. Applicant argues that the combination of Sunden and Raible do not teach the relative dimensions of the diameter, length, and position of the tube sections of variable diameter. However, pump tubes with varying diameters are known in the art, as demonstrated by Sunden and Raible. The only difference between the prior art and the instantly claimed invention is the location of the sections of increased diameter. The

combined teachings of the references suggest the desirability of a pump tube comprising both narrow and wide tube sections at various positions in the tube length in order to prevent backflow and decrease blood hemolysis. One of ordinary skill in the art would have been able to combine the teachings of Sunden and Raible with regard to moving fluid through the tube efficiently and with little trauma to the cells in order to arrive at the claimed invention, since combining the teachings in a known fashion yields a predictable result—efficient and trauma-free movement of blood through tubing lines of varying diameters. Accordingly, absent any showing of unexpected results, the combined teachings of the prior art reasonably suggest the device claimed by applicant.

Conclusion

9. Since the Examiner changed her grounds of rejection for claim 29 absent any amendment from applicant, this is a non-final rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
8 August 2007